### PATENT COOPERATION TREATY

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or age		FOR FURTHER ACT	TION	See Form PCT/IPEA/416				
60560WO (47992 International appli		International filing date (a	lav/month/vear)	Priority date (day/month/year)				
	cation 140.			25 February 2004 (25.02.2004)				
International Pater	PCT/US05/06173   25 February 2005 (25.02.2005)   25 February 2004 (25.02.2004)   International Patent Classification (IPC) or national classification and IPC							
	IPC: A01N 43/04(2006.01);A61K 31/70(2006.01)							
Applicant								
GOVERNMENT OF THE U.S.A. AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES								
1. This i Exam	report is the internat ining Authority unde	ional preliminary exami r Article 35 and transmitt	nation report, establi ed to the applicant ac	shed by this International Preliminary cording to Article 36.				
2. This I	REPORT consists of	a total of <u>'</u> sheets, inch	ıding this cover sheet	*				
3. This r	eport is also accompa	anied by ANNEXES, cor	nprising:					
a	sent to the applica	nt and to the Internation	al Bureau) a total of	sheets, as follows:				
	sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).							
	sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.							
ъ. Г								
	, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).							
4. This r	eport contains indica	tions relating to the follo	wing items:					
$\boxtimes$	_	asis of the report						
	Box No. II Priority							
	Box No. III Non-establishment of opin applicability		ion with regard to novelty, inventive step and industrial					
	-	ck of unity of invention						
Box No. V Reasoned statement under		r Article 35(2) with regard to novelty, inventive step or ations and explanations supporting such statement						
Box No. VI Certain documents cited		•						
Box No. VII Certain defects in the intern		national application						
Box No. VIII Certain observations on the		international application						
Date of submission of the demand		Date of completion of this report						
31 August 2005 (31.08.2005)			27 February 2006 (27.02.2006)					
Name and mailing address of the IPEA/ US  Mail Stop PCT, Attn: IPEA/US  Commissioner for Patents  P.O. Box 1450			Authorized officer Valence Bell-Hamp. In Patrick T. Lewis					
Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201			Telephone No. 571-2	72-1600				
	1) 273-3201 09 (cover sheet)(April 2	005)						

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/06173

Box No. I Basis of the report						
1. With regard to the language, this report is based on:						
the international application in the language in which it was filed.						
a translation of the international application into <u>English</u> , which is the language of a translation furnished for the purposes of:						
international search (under Rules 12.3 and 23.1(b))						
publication of the international application (under Rule 12.4(a))						
international preliminary examination (under Rules 55.2(a) and/or 55.3(a))						
2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):						
the international application as originally filed/furnished						
the description:						
pages 1-44 as originally filed/furnished pages* NONE received by this Authority on						
pages* NONE received by this Authority on						
the claims: pages 45-51 as originally filed/furnished						
pages 43-31 as originally international pages* NONE as amended (together with any statement) under Article 19						
pages* NONE received by this Authority on						
pages* NONE received by this Authority on						
the drawings:						
pages 1-11 as originally filed/furnished						
pages* NONE received by this Authority on						
pages* NONE received by this Authority on						
a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.						
3. The amendments have resulted in the cancellation of:						
the description, pages						
the claims, Nos						
the drawings, sheets/figs						
the sequence listing (specify):						
any table(s) related to the sequence listing (specify):						
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).						
the description, pages						
the claims, Nos.						
the drawings, sheets/figs						
the sequence listing (specify):						
any table(s) related to the sequence listing (specify):						
f item 4 applies, some or all of those sheets may be marked "superseded."						

#### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

Form PCT/IPEA/409 (Box No. V) (April 2005)

International application No. PCT/US05/06173

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
1. Statement					
Novelty (N)	Claims 1-50	YES			
	Claims NONE				
Inventive Step (IS)	Claims 1-50	YES			
. ,	Claims NONE				
Industrial Applicability (IA)	Claims 1-50	YES			
		NO			
Claims 1-50 meet the criteria set out in PCT A claimed can be made or used in industry.		ibility because the subject matte			